K000959

JUN 22 2000

Caradyne, Ltd.
Parkmore Business Centre
Parkmore West
Galway, Ireland
Tel - [353] 91-709010
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2.1 Summary of Safety and Effectiveness

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June 21, 2000

Caradyne, Ltd.
Parkmore Business Park
Parkmore West
Galway, Ireland

Tel - 011-353-91-709010
Fax - 011-353-91-758929

Official Contact: John O'Dea, Ph.D. - General Manager

Proprietary or Trade Name: Criterion 60

Common/Usual Name: Airway Pressure and Oxygen Monitor

Classification Name: Airway Pressure Monitor (includes gauges and / or alarm) and Oxygen, gaseous phase, gas analyzer

Device: Criterion 60

Predicate Devices: Caradyne, Ltd. - Criterion 40 - K992101
Mine Safety Appliance - MiniOx 3000 - K961644
Ventrex Inc. - oxygen sensor - K963415

Device Description:

The Criterion 60 is a microprocessor controlled device that measures and monitor patient airway pressure and oxygen concentration. It has low and high alarms advise the user if the measured parameters fall outside the user-set ranges. It operates on AC / DC power and provides digital and graphically readouts. It connects into the patient circuit with the use of a pressure tubing with integral in-line filter and a connector and a separate connector for the oxygen sensor.

Intended Use:

Indicated Use -- The Criterion 60 Pressure / Oxygen Monitor is indicated for use to measure airway pressures and oxygen concentrations with devices that are not capable of monitoring pressure or oxygen concentration (e.g., a resuscitation bag or basic ventilator) or as an independent backup for devices that do measure pressure or oxygen concentration.

Environment of Use -- Hospital, sub-acute institutions, and intra-hospital transport

Comparison to Predicate Devices:

Oxygen Monitoring Portion

Item	Criterion 60 (New Device)	MSA - MiniOx 3000 - K991644
Intended Use	To monitor oxygen concentration throughout the breathing cycle. For use as a standalone or backup device	To monitor oxygen concentration throughout the breathing cycle. For use as a standalone or backup device
Prescription device	Yes	Yes
Intended Patient population	Any patient the clinician desires to monitor oxygen concentration.	Any patient the clinician desires to monitor oxygen concentration.
Intended environments	Hospital, Sub-acute Institutions, intra-hospital transport	Hospital, Sub-acute Institutions, intra-hospital transport
Design features		
Size (W x H x D)	6.5" x 3.4" x 5"	5.98" x 3.26" x 1.31"
Controls	Microprocessor controlled, solid state, AC / DC adaptable	Microprocessor controlled, DC
Power specifications	120 V AC, 60 Hz, 20 W or 230 V AC, 50 Hz, 60 mA, 12 V DC	9 V battery
Output	Digital readout	Digital readout
Materials which interface with patient	PVC for the airway connector tee and ABS for the oxygen sensor	N/A
Patient interface	Airway adapter placed in the circuit	Airway adapter placed in the circuit
Display of information	Oxygen concentration Low alarm setting High alarm setting Power source and status Audible and visual alarm Calibration keys	Oxygen concentration Low alarm setting High alarm setting Power source and status Audible and visual alarm Calibration keys

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Item	Criterion 60 (New Device)	MSA - MiniOx 3000 - K991644
Performance Characteristics and features		
Low alarm range	18 to 99%	16 to 99%
High alarm range	19 to 100%	15 to 100%
Resolution	1%	1%
Accuracy	± 3% of full scale (atmospheric pressures compensated)	± 2% of full scale at known atmospheric conditions
Response time	Reaches 90% of final value w/i 10 seconds	Reaches 90% of final value w/i 20 seconds
Oxygen sensor life	Continuous use - 400,000 oxygen hours (1 year of continuous use at 45% oxygen concentration) at 25 C dry.	Over one year in normal medical conditions (nominal 750,000 O2 hours)
AC / DC operation	120 V AC / 230 V AC and 12 V DC	9 V DC battery
Alarms	Low High pressure Loss of power Low battery	Low High Low battery
Operating temperature / humidity	5 to 45 °C, 15 - 95% RH	0 to 40 °C, 5 - 95% RH
Storage temperatures	-40 to 60 °C @ 95% RH	-40 to- 70 °C @ 95% RH
Calibration	Yes	Yes
Standards		
IEC 60601-1	Yes	Yes
ISO 7767	Yes	Assumed
EN 12598	Yes	Assumed
Contraindications	None	None

Pressure Monitoring Portion

Item	Criterion 60 (New Device)	Criterion 40 - K992101
Intended Use	For use with positive pressure devices as a standalone or backup device to measure and monitor high and low airway pressures	For use with positive pressure devices as a standalone or backup device to measure and monitor high and low airway pressures
Prescription device	Yes	Yes
Intended Patient population	Any patient utilizing positive pressure devices and the clinician desires to have pressure monitoring.	Any patient utilizing positive pressure devices and the clinician desires to have pressure monitoring.

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Item	Criterion 60 (New Device)	Criterion 40 - K992101
Intended environments	Hospital, Sub-acute Institutions, intra-hospital transport	Hospital, Sub-acute Institutions, Home Care, intra-hospital transport
Design features		
Size (W x H x D)	6.5" x 3.4" x 5"	6.5" x 3.4" x 5"
Controls	Microprocessor controlled, solid state pressure transducer, AC / DC adaptable	Microprocessor controlled, solid state pressure transducer, AC / DC adaptable
Power specifications	120 V AC, 60 Hz, 20 W or 230 V AC, 50 Hz, 60 mA, 12 V DC	120 V AC, 60 Hz, 20 W or 230 V AC, 50 Hz, 60 mA, 12 V DC
Output	Digital readout of pressures	Digital readout of pressures
Materials which interface with patient	PVC, K-resin for the pressure tubing and airway connector tee	PVC, K-resin for the pressure tubing and airway connector tee
Patient interface	Airway adapter placed in the circuit or connection to a face mask	Airway adapter placed in the circuit or connection to a face mask
Display of information	Low pressure alarm setting High pressure alarm setting Status of alarm silence and time remaining Peak pressure Real-time pressure Power source and status Audible and visual alarm	Low pressure alarm setting High pressure alarm setting Status of alarm silence and time remaining Peak pressure Real-time pressure Power source and status Audible and visual alarm
Performance Characteristics and features		
Low pressure alarm range	1 - 20 cm H_2O 1 cm H_2O resolution	1 - 20 cm H_2O 1 cm H_2O resolution
High pressure alarm range	5 - 99 cm H_2O 1 cm H_2O resolution	5 - 99 cm H_2O 1 cm H_2O resolution
Peak pressure	Displayed as value	Displayed as value
Real-time pressure	Displayed as bar graph	Displayed as bar graph
Alarm delay	Yes - 1 - 20 seconds	Yes - 1 - 20 seconds
AC / DC operation	120 V AC / 230 V AC and 12 V DC	120 V AC / 230 V AC and 12 V DC
Accuracy of pressure alarm	+/- (1 + 3% of reading) rounded up to nearest cm H_2O	+/- (1 + 3% of reading) rounded up to nearest cm H_2O
Accuracy of display - Peak and Pressure bar graph	+/- (1 + 3% of reading) rounded up to nearest 0.5 cm H_2O	+/- (1 + 3% of reading) rounded up to nearest 0.5 cm H_2O

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Item	Criterion 60 (New Device)	Criterion 40 - K992101
Alarms	Low pressure High pressure Loss of power Low battery	Low pressure High pressure Loss of power Low battery
Operating temperature / humidity	5 to 45 °C, 15 - 95% RH	5 to 45 °C, 15 - 95% RH
Storage temperatures	-40 to 60 °C @ 95% RH	-40 to 60 °C @ 95% RH
Battery life	up to 24 hours for backup and transport use but primary power supply is AC	up to 24 hours for backup and transport use but primary power supply is AC
Zero calibration	Yes	Yes
Accessories		
Pressure tubing with in-line filter and airway connector	Yes	Yes
Pole mount	Yes	Yes
AC power supply	Yes	Yes
Standards		
IEC 60601-2	Yes	Yes
UL 260 / IEC 60601-1	Yes	Yes
Contraindications	None	None

Differences Between Other Legally Marketed Predicate Devices

The Criterion 60 Pressure / Oxygen Monitor is viewed as substantially equivalent to the following predicate device - Criterion 40 - Pressure monitor cleared under K992101 and Mine Safety Appliance - MiniOx 3000 cleared under K961644 and the Ventrex, Inc. - oxygen sensor cleared under K963415.

The differences between the Criterion 60 and the predicate device are minimal. There are no significant differences that affect the safety or effectiveness of the intended device as compared to the predicate devices. They are viewed as substantially equivalent to the predicate devices since they:

1. Have the same intended uses
   1.1 Intended for the measurement and monitoring patient airway pressure
   1.2 Provide high and low alarms

2. Have the same environments for use
   2.1 Used in hospitals, sub-acute institutions
   2.2 The device has been designed for stationary and intra-institution transport only.
3. Are similar in design
   3.1 Utilize the same design and functional features
4. They employ the same technology
   4.1 Utilize a pressure transducer
   4.2 Utilized tubing to interface with patient circuit
5. Are made of identical materials
   Utilize similar materials for the monitor and accessories

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 22 2000

Mr. Paul E. Dryden
Caradyne Ltd.
c/o ProMedic, Inc.
6329 W. Waterview Court
McCordsville, IN 46055-9501

Re: K000959
Criterion 60 - Pressure/Oxygen Monitor
Regulatory Class: II (two)
Product Code: CAP, CCL
Dated: March 23, 2000
Received: March 24, 2000

Dear Mr. Dryden:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2.3 INDICATIONS FOR USE

Pursuant to the Notice of February 6, 1996 regarding listing of Indications for Use on a separate sheet, the following is per that request.

510(k) Number: K000959 (To be assigned)

Device Name: Criterion 60 Pressure / Oxygen Monitor

Intended Use : The Criterion 60 Pressure / Oxygen Monitor is indicated for use to measure airway pressures and oxygen concentrations with devices that are not capable of monitoring pressure or oxygen concentration (e.g., a resuscitation bag or basic ventilator) or as an independent backup for devices that do measure pressure or oxygen concentration.

Environment of use is hospital, and sub-acute institutions. The device has been designed for stationary and intra-institution transport only.

This device should be used by trained healthcare professionals qualified in the use of such devices.

Concurrence of CDRH, Office of Device Evaluation (ODE)

[redacted]

for Division Sign-Off Mark N Melkerson
Division of Cardiovascular, Respiratory,
Neurological Devices
(ODE) Number K000959

Prescription Use ✓ **or** **Over-the-counter use** __
(Per CFR 801.109)